



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[EPA-HQ-OPP-2010-0670; FRL-9338-9]

RIN 2070-AJ80

Pesticides; Microbial Pesticide Definitions and Applicability; Clarification and Availability of Test Guideline

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule clarifies the distinction between “isolates” and “strains,” and clarifies the requirements applicable to new isolates, which are considered to be new active ingredients under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Additional revisions to regulatory text include several minor corrections to words and references. Finally, EPA is announcing the availability of a final microbial pesticide test guideline that further explains the existing data requirement to deposit a sample in a nationally recognized culture collection. Collectively, the final rule clarifications and revisions, as well as the final microbial pesticide test guideline, are expected to enhance the ability of industry to efficiently manage its microbial pesticide registration submissions.

DATES: This final rule is effective [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0670, is available either electronically through <http://www.regulations.gov> or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301

12P-0199

Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Rose Kyprianou, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5354; fax number: (703) 305-5884; email address: kyprianou.rose@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be potentially affected by this action if you are a producer or registrant of a microbial pesticide product. This action also may affect any person or company who might petition EPA for a tolerance or an exemption from the requirement of a tolerance for residues of a microbial pesticide, holds a pesticide registration with an existing tolerance or tolerance exemption for a microbial pesticide, or is interested in obtaining or retaining a tolerance or tolerance exemption in the absence of a registration (i.e., a tolerance or tolerance exemption for an imported microbial pesticide). The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. Potentially affected entities may include, but are not limited to:

- Pesticide and Other Agricultural Chemical Manufacturing (NAICS code 325320), e.g., pesticide manufacturers or formulators of pesticide products, importers, or any person or company who seeks to register a pesticide or to obtain a tolerance or tolerance exemption for a pesticide.

- Crop Production (NAICS code 111).
- Animal Production (NAICS code 112).
- Food Manufacturing and Processing (NAICS code 311).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

In the **Federal Register** of October 26, 2007 (72 FR 60988) (FRL-8109-8), a final rule, entitled “Pesticides; Data Requirements for Biochemical and Microbial Pesticides,” revised the data requirements for biochemical and microbial pesticides-- regulations that had originally been promulgated in and had remained largely unchanged since 1984. In doing so, EPA established a distinct subpart for microbial pesticides (i.e., 40 CFR part 158, subpart V) that provided a definition for these particular pesticides and clearly identified the data required to support their registration. Since 2007, however, EPA has consistently encountered questions from industry stakeholders on certain portions of 40 CFR part 158, subpart V, particularly with regard to the language set forth in 40 CFR 158.2100(c)(2).

To address these questions, in the **Federal Register** of April 15, 2011 (76 FR 21294) (FRL-8857-7), EPA proposed specific revisions to the regulatory text in 40 CFR 158.2100(c)(2) for purposes of enhanced clarity. In addition, EPA also recognized that an existing data requirement under 40 CFR 158.2120(c) and 40 CFR 158.2171(c), deposition of a sample in a nationally recognized culture collection, did not have an accompanying test guideline and that there were several minor errors in the regulatory text of 40 CFR part 158, subpart V. Therefore, with the proposed rule, EPA also made available for public comment a draft test guideline, entitled “Deposition of a Sample in a Nationally Recognized Culture Collection” and identified as OCSPP Test Guideline 885.1250, addressing the deposition of a sample in a nationally recognized culture collection data requirement, and proposed to make other minor corrections to the regulations. The public comment period for the proposed rule closed on July 14, 2011, and EPA received no comments on the proposed rule or the draft test guideline.

III. Final Changes

A. What Action is EPA Taking?

EPA is finalizing most of the changes and corrections proposed. Although no comments were received, EPA has revised a few of the originally proposed changes and corrections to further clarify the regulatory text being modified. These changes are not substantive in nature. The specific changes being promulgated with this action and the anticipated benefits of such changes are described in this final rule and the rationale supporting the revisions can be found in the proposed rule (see Unit IV. of the April 15, 2011 proposed rule).

Specifically, EPA is making several changes and corrections to the Microbial Pesticides data requirements (40 CFR part 158, subpart V). First, EPA is revising 40 CFR 158.2100(c)(2) to reduce confusion over the distinction between “isolates” and “strains” and exactly how EPA views both of these terms. To this end, EPA substitutes “active ingredient” for “strain.” The clarification to 40 CFR 158.2100(c)(2) also includes a requirement for the use of a unique identifier, as part of the microbial pesticide active ingredient taxonomic name, to allow for improved identification of company-specific registered isolates. The clarification also mentions the possibility for data citation, in lieu of data generation, should sufficient similarity be established between isolates. Moreover, after further consideration, EPA has decided against including the proposed explanatory text (i.e., “Because of the potential for variation in microorganisms”) at the beginning of the first sentence in 40 CFR 158.2100(c)(2). This phrase is not necessary or appropriate as regulatory text because it does not add anything to the regulatory provision.

Second, in conjunction with the changes detailed for 40 CFR 158.2100(c)(2), EPA is announcing the availability of a final microbial pesticide test guideline under Series 885, entitled “Deposition of a Sample in a Nationally Recognized Culture Collection” and identified as OCSPP Test Guideline 885.1250. This OCSPP test guideline is intended to explain the existing data requirement to deposit a sample in a nationally recognized culture collection found in the tables in 40 CFR 158.2120(c) and 40 CFR 158.2171(c). Additionally, to clarify this microbial deposition data requirement, EPA is adding a test note to 40 CFR 158.2120(d) and 40 CFR 158.2171(d), emphasizing the need for the continuing maintenance of a culture deposit to ensure that it remains available for the duration of an associated registration or experimental use permit in case

EPA requests a sample. This requirement already applies to all isolates; thus, the reference to “new isolates” in the proposed rulemaking was an oversight and is just “isolates” in this final rule.

Finally, to correct several minor errors, EPA is replacing “part” with “subpart” in 40 CFR 158.2100(c)(1) and removing references to a non-existing paragraph (e) that appears in 40 CFR 158.2120 and 40 CFR 158.2171.

The improved clarity and transparency resulting from the insertion of this information in 40 CFR part 158, subpart V, are expected to enhance the ability of industry to efficiently manage its microbial pesticide registration submissions. Applicants may save time and money from an improved understanding of the standards and interpretations of the definitions for the data that are needed. Having all required studies and information available to EPA at the time of application may also reduce potential delays in the registration process, thereby enabling registration of microbial pesticides sooner and allowing microbial pesticide products to enter the market sooner.

B. What is EPA's Authority for Taking this Action?

This final rule is issued under the authority of FIFRA sections 3, 5, 10, 12, and 25 (7 U.S.C. 136 *et seq.*), and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a).

C. Electronic Access to the OCSPP Test Guidelines

To access the OCSPP test guidelines referenced in this final rule electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.” You may also access the test guidelines in <http://www.regulations.gov> grouped by Series

under Docket ID numbers: EPA-HQ-OPPT-2009-0150 through EPA-HQ-OPPT-2009-0159 and EPA-HQ-OPPT-2009-0576.

IV. FIFRA Review Requirements

Pursuant to FIFRA sections 25(a) and (d), EPA has submitted a draft of this final rule to the Committee on Agriculture in the House of Representatives; the Committee on Agriculture, Nutrition, and Forestry in the United States Senate; the United States Department of Agriculture (USDA); and the FIFRA Scientific Advisory Panel (SAP). FIFRA SAP and USDA waived review of this final rule.

V. Statutory and Executive Order Reviews

This action only clarifies existing regulatory text to allow EPA and stakeholders a clearer understanding of 40 CFR part 158, subpart V. It does not otherwise impose any other requirements, involve any significant policy or legal issues, or increase existing costs. As such, EPA is not required to make special considerations or evaluations under the following statutory and Executive Order review requirements.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This is not a “significant regulatory action” under Executive Order 12866 (58 FR 51735, October 4, 1993) and was therefore not reviewed by the Office of Management and Budget (OMB) under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not impose or change any information collection burden that requires additional review by OMB under the provisions of PRA (44 U.S.C. 3501 *et seq.*). *Burden* is defined at 5 CFR 1320.3(b). An agency may not conduct or sponsor, and

a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

The revisions in this final rule involve existing information collection activities that are already approved by OMB under PRA. Specifically, the submission of data to EPA in order to establish a tolerance or an exemption from the requirement of a tolerance are currently approved under OMB Control No. 2070-0024 (EPA ICR No. 0597); the activities associated with the application for a new or amended registration of a pesticide are currently approved under OMB Control No. 2070-0060 (EPA ICR No. 0277); the activities associated with the application for an experimental use permit are currently approved under OMB Control No. 2070-0040 (EPA ICR No. 0276); and the activities associated with the generation of data for regulatory review programs are currently approved under OMB Control No. 2070-0174 (EPA ICR No. 2288).

C. Regulatory Flexibility Act (RFA)

Pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), EPA hereby certifies that this final rule does not have a significant adverse economic impact on a substantial number of small entities. Under RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. In making this determination, the impact of concern is any significant adverse economic impact on small entities because the primary purpose of regulatory flexibility analysis is to identify and address regulatory

alternatives “which minimize any significant economic impact of the rule on small entities.” 5 U.S.C. 603 and 604. Thus, an agency may certify under RFA when the rule relieves regulatory burden, or otherwise has no expected economic impact on small entities subject to the rule.

This action only clarifies existing regulatory text to allow EPA and stakeholders a clearer understanding of 40 CFR part 158, subpart V. It does not otherwise amend or impose any other requirements. As such, this final rule will not have any adverse economic impact on any entities, large or small.

D. Unfunded Mandates Reform Act (UMRA)

State, local, and Tribal governments are rarely pesticide applicants or registrants, so this final rule is not expected to affect these governments and is not expected to adversely affect the private sector. Accordingly, pursuant to Title II of UMRA (2 U.S.C. 1531-1538), EPA has determined that this action is not subject to the requirements in UMRA sections 202 and 205 because it does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and Tribal governments, in the aggregate, or for the private sector in any 1 year. In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in UMRA sections 203 and 204.

E. Executive Order 13132: Federalism

This action will not have federalism implications because it is not expected to have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the

various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

EPA is not aware of any Tribal governments that are pesticide registrants. This action will not, therefore, have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes, will not significantly or uniquely affect the communities of Indian Tribal governments, and does not involve or impose any requirements that affect Indian Tribes, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). Accordingly, the requirements of Executive Order 13175 do not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks, nor is it an “economically significant regulatory action” as defined by Executive Order 12866.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866, nor will it affect energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards that would require the consideration of voluntary consensus standards pursuant to NTTAA section 12(d) (15 U.S.C. 272 note).

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. Therefore, this action does not involve special consideration of environmental justice-related issues as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

VI. Congressional Review Act (CRA)

Pursuant to CRA (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 158

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 24, 2012.

James Jones,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

PART 158--[AMENDED]

1. The authority citation for part 158 continues to read as follows:

Authority: 7 U.S.C. 136-136y; 21 U.S.C. 346a.

2. In § 158.2100, revise paragraphs (c)(1) and (2) to read as follows:

§ 158.2100 Microbial pesticides definition and applicability.

* * * * *

(c) * * *

(1) This subpart applies to microbial pesticides as specified in paragraphs (c)(2), (c)(3), and (c)(4) of this section.

(2) Each new isolate of a microbial pesticide is a new active ingredient and must be registered independently of any similarly designated and already registered microbial pesticide active ingredient. Each new isolate for which registration is sought must have a unique identifier following the taxonomic name of the microorganism, and the registration application must be supported by data required in this subpart. This does not preclude the possibility of using data from another isolate, provided sufficient similarity is established, to support registration.

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3. In § 158.2120:

- a. Revise paragraphs (a), (b), and (c).

- b. Redesignate in paragraph (d), test notes 1 through 4 as test notes 2 through 5 and add new test note 1.

The amendments read as follows:

§ 158.2120 Microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are identified in paragraph (d) of this section.

(b) *Key.* R = Required; CR = Conditionally required; NR = Not required; MP = Manufacturing-use product; EP = End-use product; TEP = Typical end-use product; TGAI = Technical grade of the active ingredient; All = All of the above.

(c) *Table.* The table in this paragraph shows the data requirements for microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE--MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS					
Test Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product identity	R	MP	EP	--
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	--
885.1250	Deposition of a sample in a nationally recognized culture collection	R	TGAI	TGAI	1
885.1300	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	--
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	2
885.1500	Certification of limits	R	MP	EP	--
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	--

830.6303	Physical state	R	TGAI	TGAI	--
830.6304	Odor	R	TGAI	TGAI	--
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	R	TGAI	TGAI	--
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	--
830.6319	Miscibility	R	MP	EP	3
830.6320	Corrosion characteristics	R	MP	EP	4
830.7000	pH	R	TGAI	TGAI	--
830.7100	Viscosity	R	MP	EP	5
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	--

(d) * * *

1. Required for each isolate of a microbial pesticide. Isolates must be deposited with an agreement to ensure that the sample will be maintained and will not be discarded for the duration of the associated registration(s).

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4. In §158.2171:

a. Revise paragraphs (a), (b), and (c).

b. Redesignate in paragraph (d), test notes 3 through 6 as test notes 4 through 7 and add new test note 3.

The amendments read as follows:

§ 158.2171 Experimental use permit microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Notes that apply to an individual test and include specific

conditions, qualifications, or exceptions to the designated test are identified in paragraph (d) of this section.

(b) *Key.* R = Required; CR = Conditionally required; NR = Not required; MP = Manufacturing-use product; EP = End-use product; TEP = Typical end-use product; TGAI = Technical grade of the active ingredient; All = All of the above.

(c) *Table.* The table in this paragraph shows the data requirements for experimental use permit microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE--EUP MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS

Test Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product identity	R	MP	EP	--
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	1, 2
885.1250	Deposition of a sample in a nationally recognized culture collection	R	TGAI	TGAI	3
885.1300	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	2
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	2, 4
885.1500	Certification of limits	R	MP	EP	--
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	--
830.6303	Physical state	R	TGAI	TGAI	--
830.6304	Odor	R	TGAI	TGAI	--
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	R	TGAI	TGAI	--
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	--

830.6319	Miscibility	R	MP	EP	5
830.6320	Corrosion characteristics	R	MP	EP	6
830.7000	pH	R	TGAI	TGAI	--
830.7100	Viscosity	R	MP	EP	7
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	--

(d) * * *

3. Required for each isolate of a microbial pesticide. Isolates must be deposited with an agreement to ensure that the sample will be maintained and will not be discarded for the duration of the associated experimental use permit(s).

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